In re Application of:

AIZAWA et al

Serial No.: 09/830,019

Filed: September 21, 2001 Page 2

PATENT Docket No. SHIM1120

Amendments to the Claims:

Please amend claim 1 as follows.

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:** 

1. (Currently Amended) An adjuvant comprising an attenuated toxin having a residual

toxic activity of less than one-two thousandth (<1/2000) that of the natural toxin

corresponding thereto and having an activity of enhancing production of an antibody specific

to an antigen other than the attenuated toxin, prepared by attenuating a toxin, or a subunit

thereof, which retains serine residues, glutamic acid residues, and lysine residues of the

natural toxin in its natural amino acid sequence, and having a formalin molecule bound to a

lysine residue of the toxin, wherein said toxin is selected from the group consisting of cholera

toxin, pertussis toxin, heat-labile toxin of pathogenic E. coli, Staphylococcus  $\alpha$  toxin and  $\beta$ 

toxin, heat-labile toxin of pathogenic E. coli, Staphylococcus  $\alpha$  toxin and  $\beta$  toxin, and

thermostable hemolytic toxin of Vibrio parahaemolyticus.

2. (Original) The adjuvant of claim 1, wherein said toxin is a mutant having an amino

acid sequence of the corresponding natural toxin wherein one or more amino acid residues

are substituted, inserted, deleted, and/or added, and having an adjuvant activity.

3. (Original) The adjuvant of claim 1, wherein said toxin is a natural toxin.

Claims 4 and 5 (Canceled)

6. (Previously Presented) The adjuvant of claim 1, wherein said toxin is a natural

cholera toxin prepared by attenuating a natural cholera toxin with formalin treatment.

7. (Original) The adjuvant of claim 6, wherein said residual toxic activity is less than

one-ten thousandth (1/10,000) that of said corresponding natural toxin.

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Filed: September 21, 2001

Page 3

(Withdrawn) A vaccine preparation comprising the adjuvant of claim 1 and one or 8.

**PATENT** 

Docket No. SHIM1120

more vaccine antigens.

9. (Withdrawn) The vaccine preparation of claim 8, wherein said vaccine preparation is

formulated for intranasal administration.

(Withdrawn) The vaccine preparation of claim 8, wherein said vaccine preparation is 10.

formulated for oral administration.

11. (Withdrawn) The vaccine preparation of claim 8, wherein the vaccine preparation is

formulated for percutaneous administration.

(Withdrawn) The vaccine preparation of claim 8, wherein said vaccine comprises one 12.

or more antigens from one or more pathogenic microorganisms, said microorganisms selected

from the group consisting of influenza virus, rotavirus, measles virus, rubella virus, mumps

virus, AIDS virus, Bordetella pertussis, diphtheria bacillus, Helicobacter pylori,

enterohaemorrhagic Escherichia coli (EHEC), Chlamydia, Mycoplasma, Malaria parasite,

coccidium protozoa, schistosome, Clostridium tetani, hepatitis B virus, and Japanese

encephalitis virus.

13. (Previously Presented) The adjuvant of claim 1, wherein said toxin is attenuated by

chemical treatment.

14. (Withdrawn) A method of vaccination comprising administering the vaccine

preparation of claim 8 to a subject in need thereof.

15. (Withdrawn) The method of claim 14, wherein the vaccine preparation is

administered orally, intravenously, intranasally, or percutaneously.

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